

REMARKS

Upon entry of the forgoing amendment, claims 1, 2, 5-7, 10, 17, 18, 20-24, 26, 27, 43, 97-103, 105, 106, 108-129, 131, 132 and 133 will be pending in the current application. The Examiner has indicated that claims 1, 5-7, 10, 17, 18, 20-24, 26, 27, 43, 97, 102, 109-123 and 128 are withdrawn from consideration. Applicant respectfully disagrees. As indicated in the amended claims submitted herewith, only claims 1, 5, 27, and 43 are withdrawn from consideration as being directed to unelected subject matter pursuant to a Restriction Requirement. However, the remaining claims withdrawn by the Examiner were subject only to an Election of Species, and therefore upon allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitation of the allowed generic claim as provided by 37 C.F.R. 1.140 (MPEP §809.02(a)). Claims 100 and 105 are amended to correct a typographical error and new claim 133 is sought to be added. Support for new claim 133 can be found, throughout the specification, for example at page 15, lines 1-5. No new matter has been introduced, entry is respectfully requested.

I. Rejection of the claims under 35 U.S.C. § 102(b)

Claims 2, 98-101, 103, and 105-106 are currently rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Van Den Eynde (WO 00/66764). Applicant respectfully disagrees. Van Den Eynde discloses methods for administering 1-methyl-DL-tryptophan and NOT compositions consisting essentially of 1-methyl-D-tryptophan as required by the current claims. As noted by the Examiner, the transitional phrase "consisting essentially of" " limits the

scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original). The current specification states "the [D]-isomer of 1MT was found to be effective at one quarter of the dose used for the racemic preparation." See Specification at page 53, lines 12-13. Thus, in this instance it is clear that the presence of the L isomer in the racemic mixture materially affects the basic and novel characteristics of the invention. Therefore, a method of administering a composition comprising the racemic mixture of 1-methyl-tryptophan, as in Van Den Eynde would not be encompassed by a method of administering a composition *consisting essentially of* 1-methyl-D-tryptophan as claimed herein. Withdrawal of this rejection is earnestly solicited. Without agreeing with the rejection, Applicant notes that new claim 133 has been submitted. This claim clearly excludes the use of the racemic mixture as employed by Van Den Eynde as it is directed to the use of a composition that is substantially free of the L isomer.

II. Rejection of the Claims under 35 U.S.C. § 112, First Paragraph

Claims 2, 98-101, 103, 105-106, 108, 124-127, 129, and 131-132 are rejected under 35 U.S.C. § 112, first paragraph as allegedly not being enabled by the specification. Applicant respectfully disagrees. Applicant submits herewith a Declaration under 37 C.F.R. 1.132 of Dr. Mario Mautino discussing the results of an experiment performed by him which clearly shows the efficacy of 1-methyl-D-tryptophan in the absence of an additional chemotherapeutic agent. Additionally, the Declaration discusses data presented in an article by Hou, *et al.*, (copy submitted herewith) which also clearly depicts the efficacy of a method of administering a

composition consisting essentially of 1-methyl-D-tryptophan. Based on the data presented and the statements made in Dr. Mautino's Declaration, it is clear that administration of compositions consisting essentially of 1-methyl-D-tryptophan in the absence of any additional therapeutic agents is effective in delaying the relapse or progression of a tumor as claimed, as evidenced by lung and melanoma tumor models. Withdrawal of this rejection is earnestly solicited.

CONCLUSION

In view of the foregoing, Applicant respectfully submits that no further impediments exist to the allowance of this application and, therefore, requests an indication of allowability. However, the Examiner is requested to call the undersigned if any questions or comments arise.

The Director is hereby authorized to charge any appropriate fees under 37 C.F.R. §§1.16, 1.17, and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 50-1283.

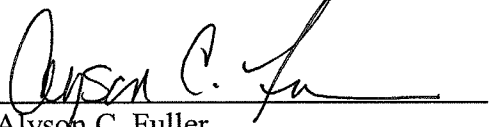
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COOLEY GODWARD KRONISH LLP
ATTN: Patent Group
777 6th Street NW, Suite 1100
Washington, DC 20001

Tel: (202) 728-7129
Fax: (202) 842-7899

Respectfully submitted,
COOLEY GODWARD KRONISH LLP

By:


Alyson C. Fuller
Reg. No. 61,844